

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing
(day/month/year) - 4 JAN 2006

Applicant's or agent's file reference
FP2484/CKM

IMPORTANT NOTIFICATION

International application No.
PCT/SG2004/000416

International filing date (day/month/year)
17 December 2004

Priority date (day/month/year)
17 December 2003

Applicant

AGENCY FOR SCIENCE, TECHNOLOGY AND RESEARCH et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP2484/CKM	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/SG2004/000416	International filing date (<i>day/month/year</i>) 17 December 2004	Priority date (<i>day/month/year</i>) 17 December 2003
International Patent Classification (IPC) or national classification and IPC Int. Cl. <i>C12Q 1/68 (2006.01)</i> <i>C12N 15/50 (2006.01)</i>		
Applicant AGENCY FOR SCIENCE, TECHNOLOGY AND RESEARCH et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ (sent to the applicant and to the International Bureau) a total of 6 sheets, as follows:

☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 7 October 2005	Date of completion of this report 21 December 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer LEXIE PRESS Telephone No. (02) 6283 2677

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SG2004/000416

Box No. I Basis of the report

1. With regard to the language, this report is based on:

☒ The international application in the language in which it was filed

☐ A translation of the international application into
translation furnished for the purposes of:

, which is the language of a

☐ international search (under Rules 12.3(a) and 23.1 (b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages 1-31 as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* 32-37 received by this Authority on 7 October 2005 with the letter of 6 October 2005

pages* received by this Authority on with the letter of

☒ the drawings:

pages 1/5-5/5 as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/figs

☐ the sequence listing (*specify*):

☐ any table(s) related to the sequence listing (*specify*):

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SG2004/000416

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-22	YES
	Claims	NO
Inventive step (IS)	Claims 1-22	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-22	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The present invention relates to primers for the amplification of segments from the ns1 region of the SARS coronavirus and the use of the primers in PCR based diagnostic tests for SARS-CoV.

The following documents cited in the International Search Report have been considered for the basis of this report:

D1 Ruan et al (2003) The Lancet. Vol 361(9371): 1779-1785

D2 WO 2004085455 A1

D3 WO 2004099440 A1

D4 WO 2005005658 A1

D5 Snijder et al. (2003) Journal of Molecular Biology. Vol 331: 991-1004

D6 Yam et al. (2003) Journal of Clinical Microbiology. Vol 41(10): 4521-4524

D7 Poon et al (2003) Clinical Chemistry. Vol 49(6): 953-95

Novelty and Inventive Step

D1 is the only category X citation cited in the search report. D1 teaches the full-length genomic sequence of 14 SARS-CoV isolates and compares SARS-CoV sequences with the sequence of coronaviridae from other species. The citation indicates the position and frequency of nucleotide variations, including variations in the ns1 region, in the 14 isolates.

D1 does not teach or suggest improved SARS-CoV, PCR based diagnostics selective for the region of the SARS coronavirus genome from nucleotide 4609 to nucleotide 4765 or from nucleotide 6652 to nucleotide 7003, or the specific amplification primers set forth in SEQ ID NOS: 3, 4, 6, 7, 9 and 10.

Therefore the subject matter of claims 1-22 meets the criteria set forth in PCT Article 33(2) for novelty and PCT Article 33(3) for inventive step.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

<u>Application No.</u> <u>Patent No.</u>	<u>Publication date</u> <u>(day/month/year)</u>	<u>Filing date</u> <u>(day/month/year)</u>	<u>Priority date (valid claim)</u> <u>(day/month/year)</u>
WO 2004085455	7 October 2004	24 March 2004	23 March 2003
WO 2004099440	18 November 2004	9 May 2003	9 May 2003
WO 2005005658	20 January 2005	14 July 2003	14 July 2003

Each document was published after the priority date of the present application, however their priority dates precede the priority of the present application. As such each citation may be relevant at national phase examination as a whole of contents citation.

WO 2004085455 discloses the entire genomic DNA sequence of the SARS virus strain HKU-39849 (SEQ ID NO: 15) and a method for detecting the virus in a sample by RT-PCR using primers derived from a nucleotide sequence of the SARS virus. Consequently, WO 2004085455 may be relevant to the novelty of the claims at national phase examination.

(continued in Supplemental Box)

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure</u> <u>(day/month/year)</u>	<u>Date of written disclosure</u> <u>referring to non-written disclosure</u> <u>(day/month/year)</u>
<hr/>	<hr/>	<hr/>

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☒ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment* on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: VI (Certain Documents Cited)

WO 2004099440 discloses methods, including RT-PCR, for detecting the presence of SARS in a sample. Primers for use in the method are exemplified in Table 4. Many of the primers, such as PMSU_00002 are derived from the *nsp1* gene. As such, WO 2004099440 may be prejudicial to the novelty of the present claims during national phase examination.

WO 2005005658 teaches similar methods and primers to those disclosed in WO 2004099440. Primers for the amplification of the SARS virus are exemplified in Table 18 and include several primers that span the *nsp1* gene. WO 2005005658 may be prejudicial to the novelty of the present claims during national phase examination.